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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :
A61B 5/20, 10/00, G01N 1/10

A1

(11) International Publication Number: WO 86/ 03394

(43) International Publication Date: 19 June 1986 (19.06.86)

(21) International Application Number: PCT/GB85/00576

(22) International Filing Date: 12 December 1985 (12.12.85)

(31) Priority Application Number: 8431388

(32) Priority Date: 12 December 1984 (12.12.84)

(33) Priority Country: GB

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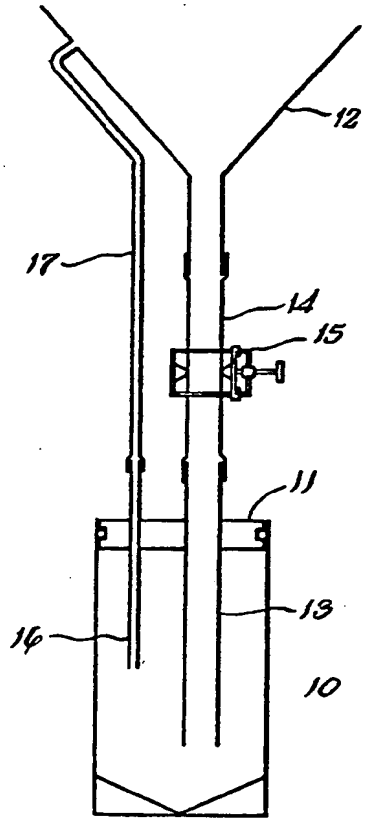
(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB, IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US.

Published
With international search report.

(54) Title: A LIQUID SAMPLING DEVICE

(57) Abstract

A device for separating a predetermined initial volume of a liquid stream such as urine whilst being passed, comprising a container (10) a closure member (11), the latter adapted to receive an inlet tube (13) connected to a funnel (12), and a capillary tube (16) connected via a further tube (17) to the interior of funnel (12). A shut-off valve (15) acts on a length of flexible tubing (14). The liquid sample is delivered by the funnel (2) and inlet tube (13) into container (10) until the level reaches the bottom of capillary tube (16), whereupon substantially no further liquid can enter the container (10). The shut-off valve (15) is then closed to prevent any further liquid from passing down the inlet tube (13). Thus, a known initial volume determined by the height of capillary tube (16) is collected.



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A LIQUID SAMPLING DEVICE

THIS INVENTION concerns a device for collecting a predetermined sample from a stream of liquid. More particularly, the device is intended for the separation of an initial 10ml or so of urine from the remainder of a sample thereof.

In the study and diagnosis of male urinary tract infections, there is a requirement for the separation of three distinct portions of a urine sample. These are known as VB1, the first 10ml of a sample; VB2, or midstream urine, which is a volume of the urine passed after VB1; and VB3 which represents the first 10ml of a sample passed shortly after a prostatic massage has been performed.

These distinct samples may be used to diagnose infection and localise it to the urethra, the prostate or the bladder. Correct treatment of the infection would depend upon its location, and localisation is based upon a comparison of bacterial isolation and leucocyte numbers in the different samples.

Samples VB1 and VB3 represent urethral washings, the latter being expected to contain a representative sample of prostatic fluid. For the concentration of leucocytes or bacteria to be meaningful, the volume collected should be reproducible from patient to patient.

A recent technique is to measure the zinc content of sample VB3, since this gives an indication as to the secretory activity of the prostate.

Samples are conventionally obtained using a marked container and instructing a patient to cease urinating when the liquid level reaches the mark. This is found to be neither accurate nor reproducible, particularly in the collection of sample VB3.

An object of the present invention is to provide a device which will automatically separate the first 10mls of a urine sample from that which follows, without any patient intervention. It will be preferable also for the device to be sufficiently inexpensive in manufacture, to be made available as a disposable item.

According to the present invention, there is provided, a device for separating a predetermined initial volume of a liquid sample, comprising a container, an air-tight closure member for the container, an open-ended inlet tube passing through said closure member for introducing liquid into the container and a capillary tube also passing through the closure member and open-ended to permit displacement of air therefrom, the end of the capillary tube within the container being disposed above the base thereof at a higher level than that of the inlet tube and

at a predetermined distance from the base such that filling of the container, via said inlet tube, above the end of the capillary tube is substantially prevented, whereby to enable a predetermined volume of liquid to be collected.

An embodiment of the invention will now be described, by way of example only, with reference to the accompanying schematic drawing of a device for the automatic collection of initial urine samples, in accordance with the invention.

The requirement of the device is the separation of the first 10ml or so of urine from the remainder of the sample. The actual volume is not of critical importance, but the reproducibility is.

The device comprises a chamber 10 in the form of a sterile disposable polystyrene bottle, having, say, 30ml capacity. The bottle has a closure member 11 which is adapted to produce an air-tight seal thereon.

A funnel 12 or like receptacle is connected to an inlet tube 13, preferably of a rigid or semi-rigid material, and having an internal diameter of 5mm to 6mm, which passes through the air-tight closure member 11 and is terminated some distance above the base of the container 10. Interposed between the funnel 12 and the inlet tube 13 is a section of resilient tubing 14 to which is applied a

shut-off valve 15, preferably of a type capable of one-handed operation (push to close, push and release to open).

A capillary tube 16 having an internal diameter in the region of 1mm to 2mm also passes through closure member 11, is open-ended and is connected via a further tube 17 of similar diameter to the interior of funnel 12. The lower end of capillary tube 16 within container 10 is disposed at such a height above the base of the latter that the intervening volume is just less than 10ml for a purpose to be described. The lower end of inlet tube 13 is disposed below that of tube 16.

A container 10 may be provided with a supplementary air-tight closure cap (not shown) which can be applied after removal of the closure member 11 and tubes 13 and 16, or alternatively, the member 11 may be left in situ. In use, with the valve 15 of the device in its open position, a patient is instructed to urinate into the collecting funnel 12 until the liquid level has reached approximately half way up the funnel. The initial urine representing sample VB1 flows directly into the container 10 until the liquid level rises to the lower end of capillary tube 16 whereupon further displacement of air through the tube 16 is prevented which in turn substantially prevents further entry of urine into the container. The capillary tube offers substantial

resistance to the liquid attempting to rise therein, and the maximum level to which liquid can, in any case, rise in the tubes 16 and 17 is equivalent to the level of liquid in the funnel 12. Even at this level the volume of liquid in the tubes 16 and 17 is negligible for the purpose of the sample.

Once the sample is taken, valve 15 is closed and the assembly, with or without tubes 13 and 16, is removed from the container which then may be sealed for subsequent analysis of the sample. Liquid remaining in funnel 12 is disposed of.

It is not intended to limit the invention to the above example only, many variations, such as might readily occur to one skilled in the art, being possible without departing from the scope of the invention.

For example, the capillary tube 16 may be adjustably located in closure member 11 and have graduated markings to enable the volume of the sample to be regulated.

For practical purposes it is envisaged that the assembly comprising all but the container 10 in the drawing, may be provided, pre-assembled, in a sterile package, and inserted for use into a standard container after removal of its closure cap, and the said assembly may

be disposed of after use. Conveniently, the assembly will be made entirely from plastics in order to minimise the cost of manufacture.

CLAIMS

1. A device for separating a predetermined initial volume of a liquid sample, comprising a container, an air-tight closure member for the container, an open-ended inlet tube passing through said closure member for introducing liquid into the container and a capillary tube also passing through the closure member and open-ended to permit displacement of air therefrom, the end of the capillary tube within the container being disposed above the base thereof at a higher level than that of the inlet tube and at a predetermined distance from the base such that filling of the container, via said inlet tube, above the end of the capillary tube is substantially prevented, whereby to enable a predetermined volume of liquid to be collected.

2. A device according to Claim 1, wherein said inlet tube includes a shut-off valve container to close the tube and thus isolate the volume of liquid collected.

3. A device according to Claim 2, wherein a funnel or like receptacle is connected to said inlet tube, there being between the funnel and the inlet tube a length of resilient tubing closable by means of said shut-off valve, the latter being outside of the container and of a type capable of one-handed operation.

4. A device according to Claim 3, wherein the

capillary tube communicates with the interior of the funnel.

5. A device according to Claim 3 or Claim 4, wherein the funnel and the shut-off valve are detachable from the inlet tube and the capillary tube.

6. A device according to Claim 3 or Claim 4, wherein the assembly comprising the inlet tube, the capillary tube, the funnel and the shut-off valve, is detachable from the container.

7. A device according to Claim 1, wherein the container is in the form of a sterile disposable polystyrene bottle having a capacity of or in the region of 30ml, and the closure member is air tight on the bottle.

8. A device according to Claim 1, wherein the inlet tube has an internal diameter of 5mm to 6mm.

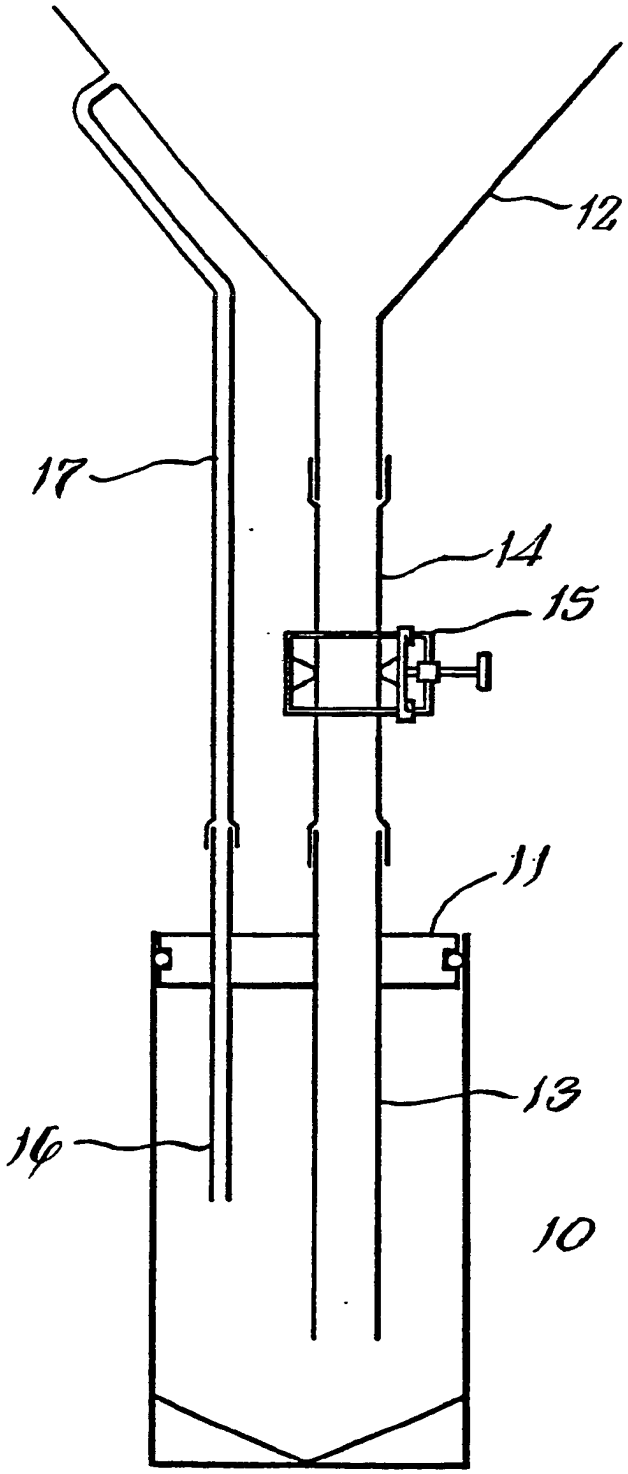
9. A device according to Claim 1, wherein the capillary tube has an internal diameter in the region of 1mm to 2mm.

10. A device according to Claim 1, wherein the capillary tube is adjustably located in the closure member and includes graduated markings to enable the volume of the

sample to be regulated.

11. A device according to Claim 1, in which the distance between the end of the capillary tube and the base of the container is such that the intervening volume is just less than 10ml.

12. A device according to any preceding claim, wherein all parts thereof are made from plastics.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INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 85/00576

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 B 5/20; A 61 B 10/00; G 01 N 1/10

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols	
IPC[4]	A 61 B 5/00	G 01 F 11/00
	A 61 B 10/00	G 01 N 33/00
	G 01 N 1/00	

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	CH, A, 304674 (OBRIST) 1 April 1955, see page 1, lines 18-29,33-59; page 2, lines 6-26; figure 1	1,2,4,6,10
X	GB, A, 2098487 (STA TESIL) 24 November 1982, see page 1, lines 31-41,60-101; page 2, lines 6-32 ; claim 1; figures 2-4	1,12
A	GB, A, 128834 (PACKARD MOTOR COMPANY) 24 July 1919, see page 1, line 16 - page 2, line 18; page 3, lines 21-29; claim 1; figures 1,2	1,4
A	US, A, 3420107 (L.R. ROWETT) 7 January 1969, see column 1, lines 35-40 and 50 - column 2, lines 4,17-24; figure 2	7,12

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* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
6th March 1986	01 AVR. 1986
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	M. VAN MOL

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT O

INTERNATIONAL APPLICATION NO. PCT/GB 85/00576 (SA 11697)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 21/03/86

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
CH-A- 304674		None	
GB-A- 2098487	24/11/82	FR-A,B 2505677	19/11/82
GB-A- 128834		None	
US-A- 3420107	07/01/69	GB-A- 1112715	

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82